the ointment, accurately weighed, into a high-speed glass blender. Add that quantity of alcohol U.S.P. XX which is sufficient to obtain a stock solution of convenient concentration. Blend 3 to 5 minutes. Make proper estimated dilutions of an aliquot to the reference concentration with alcohol U.S.P. XX. The content of gramicidin is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of gramicidin that it is represented to contain.

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

[39 FR 19046, May 30, 1974, as amended at 47 FR 23710, June 1, 1982]

§444.542k Neomycin sulfate-polymyxin B sulfate-hydrocortisone acetate cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate-hydrocortisone acetate cream contains, in each gram, neomycin sulfate equivalent to 3.5 milligrams of neomycin, polymyxin B sulfate equivalent to 10,000 units of polymyxin B, and 5.0 milligrams of hydrocortisone acetate in a suitable and harmless vehicle. Its neomycin sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain. Its polymyxin B sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. The neomycin sulfate used conforms to the standards prescribed by §444.42(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by §448.30(a)(1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identify.

(*b*) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(*c*) The batch for neomycin content and polymyxin B content.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay; potency*—(1) *Neomycin content.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Transfer an accurately weighed representative portion of the sample into a high-speed glass blender jar containing 1.0 milliliter polysorbate 80 and sufficient 0.1 *M* potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with solution 3 to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(2) *Polymyxin B content.* Proceed as directed in §436.105 of this chapter, except add to each concentration of the polymyxin B standard response line a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Prepare the sample for assay as follows: Transfer an accurately weighed representative portion of the sample into a high-speed glass blender jar containing 1.0 milliliter polysorbate 80 and sufficient 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

[50 FR 15108, Apr. 17, 1985, as amended at 55 FR 11584, Mar. 29, 1990]